

### **REMARKS**

Claims 1-18 are pending in this application as filed. Claims 1, 2 and 18 are amended and claim 17 is cancelled herein. Claims 1 and 15 remain independent.

Claims 1, 2, and 18 stand objected to on informality grounds. Claims 1, 2, and 18 are amended to address each of the noted concerns.

Claim 18 stands rejected under 35 USC §112, 2<sup>nd</sup> paragraph, as indefinite. Claim 18 is amended to clarify that the release means is the release means of the end member.

Claims 1, 2, 5-16 and 18 stand rejected under 35 USC §102(b), as anticipated by Barker, et al. (U.S. Patent No. 6,569,115). Claim 17 stands rejected under 35 USC §102(b), as anticipated by Shaw (U.S. Patent No. 6,090,077). Claims 1, 2, and 14-18 stand rejected under 35 USC §102(e), as anticipated by Shue, et al. (U.S. Patent No. 6,921,386). Claim 3 stands rejected under 35 USC §103(a), as obvious over Barker, et al. in view of Shaw, and also as obvious over Shue, et al.

The rejections relating to claim 17 are moot, in view of its cancellation. The rejections of claims 1-16 and 18 are respectfully traversed.

#### **Non-Anticipation by Barker**

It is respectfully submitted that the retraction of the needle of Barker is achieved through the use of a spring. See column 7, lines 59-61.

By contrast, independent claims 1 and 15 of the application are directed towards a cannula/catheter introducer or inserter having the inner tubular member under vacuum, with the vacuum functioning to retract the end member into the inner tubular member.

Barker discloses only two embodiments (see Abstract), one of which requires manual retraction and the other of which provides for automatic retraction using the above referenced spring.

It is therefore respectfully submitted that Barker lacks any disclosure or suggestion of an inner tubular member under vacuum as required by the independent claims, and hence by all claims now under examination. Indeed, such an arrangement is entirely unnecessary in the device of Barker and would violate a principle of operation

of Barker, as it is the spring in Barker that causes the automatic retraction of the needle. It is further respectfully submitted that one skilled in the art would understand, based on the presence of a spring in the device of Barker, that Barker actually teaches away from the vacuum arrangement recited in claims 1 and 15 of the present application.

Further still, it is respectfully submitted that the device of Barker is a pre-filled syringe device with a retractable needle. This is a very different device than the cannula/catheter introducer claimed in claim 1 and inserter of claim 15 of the present application, and one skilled in the art would immediately understand that the device of Barker would be entirely unsuitable for use as a cannula/catheter introducer or inserter.

Given that Barker discloses a device that would be unsuitable for use as a cannula/catheter introducer, and fails to disclose all of the explicitly recited features of the present invention, it is respectfully submitted that the present claims are both novel and non-obvious over the applied Barker.

#### Non-Anticipation by Shue

Turning now to the disclosure of Shue, it is respectfully submitted that this reference neither discloses nor suggests that the end member comprises sealing means that sealingly engage with the inner tubular member together with release means moveable between first and second positions to lock the end member to, and to unlock the end member from, the inner tubular member.

Shue discloses an end member that is sealingly engaged to the plunger body, with the engagement achieved through a friction connection. See column 5, lines 46-59, and column 6, lines 9-48. According to Shue, it is movement of the anchoring end of 3122 of the tubular needle seat 31 from the hook-up to the depressed position that results in depression of the anchored portion 432 of the seal member to rip the seal line and thereby release the seal member 43 from the plunger body, thus allowing the seal member 43, along with the needle cannula 32 to be sucked into/towards the cavity 41 of the plunger body.

Thus, it is respectfully submitted that there is no disclosure by Shue of release means movable between first and second positions to both lock and unlock the end member to and from the inner tubular member.

It is further respectfully submitted that Shue also fails to disclose or suggest release means on a needle holder that are moveable between first and second positions to lock the needle holder to, and to unlock the needle holder from, the outer tubular member.

Shue discloses a needle holder and an end member that engage with one another via a screw-threaded portion engagement, with the engagement achieved through a rotation of the outer tubular member. See column 5, lines 13-20 and 46-54, and column 6, lines 9-13.

Thus, it is also respectfully submitted that there is no disclosure by Shue of release means movable between first and second positions to both lock and unlock the needle holder to and from the outer tubular member.

Given that Shue fails to disclose all of the features of the present invention, it is respectfully submitted that the present claims are both novel and non-obvious over the applied Shue.

In view of the foregoing, it is respectfully submitted that the application is in condition for allowance and an early indication of the same is courteously solicited. The Examiner is respectfully requested to contact the undersigned by telephone at the below listed local telephone number, in order to expedite resolution of any remaining issues and further to expedite passage of the application to issue, if any further comments, questions or suggestions arise in connection with the application.

To the extent necessary, Applicants petition for an extension of time under 37 CFR § 1.136. Please charge any shortage in fees due in connection with the filing of

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this paper, including extension of time fees, to the Deposit Account No. 01-2135  
(Case No. 1397.45737X00) and please credit any excess fees to such Deposit Account.

Respectfully submitted,  
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